

CHAPTER 52
BIRTH CENTERS

481—52.1(135G) Definitions. For the purpose of these rules the definitions set out in Iowa Code section 135G.2 shall be considered to be incorporated verbatim in the rules. The use of the word “shall” indicates that standard is mandatory.

481—52.2(135G) License. Each facility shall obtain a license (Form 427-0059) from the department. This license shall be:

1. Posted in each facility so the public can see it easily, (III)
2. Valid only for the premises and person named on the license and not be transferable, and (III)
3. Valid for one year from the date of issuance.

52.2(1) To obtain a birth center license for a facility not currently licensed as a birth center the applicant shall:

- a. Submit application (Form 427-0087) to the department.
- b. Meet all of the requirements contained in this chapter.
- c. Submit a letter of intent and a written description of programs and services to be provided.
- d. Submit a floor plan which accurately reflects the current status of the building. The floor plan

shall show:

- (1) Room areas in proportion,
- (2) Room dimensions,
- (3) Bathrooms,
- (4) Window and door locations, and
- (5) Use of each room.
- e. Submit a photograph of the front and side elevations of the facility.
- f. Submit the license fee of \$15.
- g. Comply with state and local statutes and ordinances applicable at the time of licensure.
- h. Have on record a certificate signed by the state fire marshal or deputy state fire marshal which states that fire safety requirements have been met.
- i. Submit a report of the most recent approved water test as required by the department of natural resources for public water supplies, if the water supply is from a private source.
- j. Arrange for storage of drugs and pharmaceuticals in consultation with the board of pharmacy.
- k. Assure laboratory services by having:
 - (1) A laboratory on the premises supervised by the medical director, or
 - (2) A signed agreement with a laboratory supervised by a pathologist.
- l. Obtain a certificate of need from the health facilities council.

52.2(2) To renew a license the applicant shall:

- a. Meet requirements set out in 52.2(1) “f,” “g,” “h,” and “i.”
- b. Submit a description of changes in program and services to be provided and changes in the facility, and

c. Submit application (Form 427-0087) to the Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319, 90 days before the renewal date on the current license.

52.2(3) Variances. A variance from these rules may be granted by the director of the department.

a. To request a variance the licensee shall:

- (1) Submit request for variance (Form 427-0080) to the department of inspections and appeals at the address above,
- (2) Cite the rule or rules from which a variance is desired,

- (3) State why compliance with the rule or rules cannot be accomplished,
- (4) Explain alternate arrangements or circumstances which justify the variance, and
- (5) Demonstrate that the requested variance will not endanger the health, safety or welfare of any client.

b. Upon receipt of request for a variance the director shall:

- (1) Evaluate the alternate arrangements or circumstances which are presented,
- (2) Study the probable effect of the requested variance on the health, safety, or welfare of the client, and

(3) Consult with the applicant if additional information is required.

52.2(4) Based on these factors, the variance shall be either granted or denied within 45 days of receipt of request. Variances that are granted may be reviewed at the discretion of the director and revoked as deemed necessary. The approved variance shall remain in effect as long as alternate arrangements or circumstances continue to maintain the health, welfare, and safety of the clients.

52.2(5) Change of ownership. When a birth center is to be sold, transferred, assigned, or leased, the licensee shall:

a. Notify current clients of the pending action at least 30 days before action is taken.

b. Inform the department of the name and address of the purchaser, transferee, assignee or lessee at least 30 days before the action is to be taken, and

c. Submit a written authorization for the department to release requested information, except that which identifies individual mothers or children, to the prospective purchaser, transferee, assignee, or lessee.

(1) Information released shall not include identification of individual clients, and

(2) The purchaser may be obligated to pay for copies of documents.

d. To obtain a license when the ownership of a currently licensed birth center changes, the new applicant shall:

(1) Meet all requirements of 52.2(1)“a” through “j”; and

(2) Submit application (Form 427-0087) to the department at least 30 days prior to the planned change of ownership.

52.2(6) At least 60 days before a birth center is physically altered, modified, or expanded the licensee shall submit plans to the department for recommendations and approval.

52.2(7) A birth center license may be denied, suspended or revoked if the department finds that a facility has failed to comply with 481—Chapter 52 or Iowa Code chapter 135G.

a. Notice. When the department denies, suspends or revokes a license, the licensee or applicant shall be notified by registered mail or by personal service.

b. Hearing. The applicant or licensee may request a hearing on the decision of the department.

(1) The request must be in writing and must be mailed within 30 days of the receipt of the notice to: Department of Inspections and Appeals, Division of Health Facilities, Lucas State Office Building, Des Moines, Iowa 50319.

(2) The status of the license remains until the final agency action is taken.

(3) The hearing shall be held pursuant to 481—50.6(10A).

c. Appeal. The decision of the hearing officer is a proposed decision and becomes final unless appealed to the director within ten days pursuant to 481—50.6(10A).

52.2(8) Penalties. When a facility is found to be in violation of Iowa Code chapter 135G or 481—Chapter 52, the department may:

a. Impose a fine in an amount up to \$500 per day. Determination of the amount of the fine is based on:

(1) The severity of the violation, including the probability that death or serious harm to the health and safety of any person will result or has resulted,

(2) The extent to which the provisions of this chapter and other administrative rules were violated,

(3) Actions taken by the licensee to correct the violations or to remedy situations complained about,

(4) Any previous violations by the licensee.

b. Issue an emergency order immediately suspending or revoking a license when the department determines that any condition in the licensed birth center presents a clear and present danger to the public health and safety.

c. Impose an immediate moratorium on elective admissions to any licensed birth center when the department determines that any condition in the birth center presents a threat to the public health and safety.

d. Maintain action in the name of the state for injunction or other process to enforce Iowa Code chapter 135G and 481—Chapter 52.

Any person who establishes, conducts, manages or operates any birth center without a license shall be guilty of a simple misdemeanor. Each week of continuing violation after conviction shall be considered a separate offense. The department shall enjoin an unlicensed birth center from operating.

481—52.3(135G) Direction. Each birth center, whether organized as a proprietary or voluntary service under sole ownership or corporate group, shall have a governing body with full authority and responsibility for overall policy and fiscal management of the facility and services. The governing body shall:

1. Develop and make available to the department a table of organization.
2. Be responsible for the appointment of the director of the birth center.
3. Adopt bylaws which include criteria for staff and consultation appointments, delineation of clinical privileges and organization of staff.

481—52.4(135G) Staff requirements. There shall be sufficient professional staff to provide services for operation and maintenance of the birth center.

52.4(1) Clinical staff shall be on duty at all times when clients are present. All clinical staff members and consultants shall hold valid Iowa licenses.

52.4(2) A licensed nurse midwife or licensed physician shall attend each birth. A second nurse or physician shall also be present at each birth. All licensed staff shall be certified annually in basic life support.

52.4(3) Any staff member or volunteer not licensed as a nurse, nurse midwife or physician shall be trained by and be under the supervision of a professional staff member.

52.4(4) Health examinations for all personnel shall be required at the commencement of employment and at least every four years thereafter. The examination shall include, at a minimum, the health and tuberculosis status of the employee.

481—52.5(135G) Client selection. Each client served at a birth center shall be confirmed as having a low-risk pregnancy by her physician. The client shall begin prenatal care before 20 weeks after conception. The following list of complications of pregnancy shall require the midwife at the birth center to call and confer with the client's consulting physician to determine if the pregnancy continues to be low risk:

52.5(1) Previous history.

- a.* One or more previous premature labors or history of low birth weight infants (less than 2500 grams),
- b.* Excessively large previous infants (greater than 4000 grams),
- c.* Cesarean section,
- d.* Neonatal loss,
- e.* Two or more abortions,

- f. Fetal loss,
- g. Suspected incompetent cervix,
- h. Medical indication for termination of pregnancy,
- i. Diagnosed abnormalities of genital tract,
- j. Need for special neonatal care,
- k. Infant with a known or suspected genetic or familial disorder or mental retardation,
- l. Severe emotional problem associated with pregnancy or delivery,
- m. Hepatitis B;
- n. HIV status.

52.5(2) Early pregnancy.

- a. Maternal diabetes mellitus,
- b. Client less than 18 or more than 35 years of age,
- c. Psychiatric disorder,
- d. Marked nutritional abnormality (obesity, abnormal stature, low weight for height, etc.),
- e. Malignancy,
- f. Unresponding urinary tract infection,
- g. Suspected ectopic pregnancy,
- h. Suspected missed abortion,
- i. Severe hyperemesis,
- j. Exposure to teratogens (radiation, infection, chemicals),
- k. Positive serologic test for syphilis,
- l. Pregnancy complicated by medical disease (endocrine, renal, cardia, hypertensive, etc.),
- m. Anemia not responsive to iron therapy,
- n. Drug addiction,
- o. Vaginal bleeding or unusual abdominal pain.

52.5(3) Late pregnancy.

- a. Third trimester uterine bleeding,
- b. Toxemia of all classes,
- c. Polyhydramnios or oligohydramnios,
- d. Antepartum fetal death,
- e. Thromboembolic disease,
- f. Multiple pregnancy,
- g. Need for fetal maturation studies,
- h. Inappropriate fetal growth for gestational age (too small or too large),
- i. Persistent abnormal presentation,
- j. Postdate pregnancy of 42 weeks,
- k. Rupture of membranes for more than 12 hours without labor, or evidence of amnionitis or sepsis at any time,
- l. Premature labor (less than 36 weeks of gestation),
- m. Induction of labor,
- n. Tumor or other obstruction of birth canal,
- o. Suspected fetopelvic disproportion,
- p. Clinical evidence of active herpes disease.

52.5(4) Intrapartum.

- a. Inadequate progress in labor, suspected feto-pelvic disproportion or abnormal presentation,
- b. Need for operative delivery,
- c. Fetal distress suspected by abnormality of the fetal heart rate, fetal acidosis, or passage of meconium,
- d. Fever or suspected amnionitis or sepsis,
- e. Umbilical cord prolapse,
- f. Any conditions listed in the previous subrule which appear first during labor,
- g. Rh isoimmunization,
- h. Identified fetal anomaly.

481—52.6(135G) Consultation. Each client shall have a consulting physician who currently has privileges to provide obstetrical services in a licensed hospital. The client shall be examined by the consulting physician at least twice during her pregnancy, at the time she enters care and during the third trimester.

52.6(1) The consulting physician shall sign an agreement with the birth center to provide advice and services.

52.6(2) The client shall have a consulting physician who currently has hospital pediatric privileges and who agrees to provide consultation and care for the newborn baby.

481—52.7(135G) Transfer to hospital. If complications arise during labor or birth or following birth, the mother or baby shall be transferred to a hospital for obstetrical or newborn care.

52.7(1) The birth center shall have a signed agreement with the participating hospitals stating that transferred mothers and babies will be accepted for admission if problems arise during labor, birth, or soon after birth. This agreement shall be reviewed and signed annually.

52.7(2) The birth center shall develop a written policy and procedure for arranging transfer to a hospital.

a. The birth center shall maintain a list of available neonatal and adult transportation services including ground and air ambulance services with the qualifications of each service and telephone numbers.

b. This list shall be posted near appropriate telephones.

c. These lists and the transfer protocols shall be reviewed and updated annually.

52.7(3) The birth center shall ensure that ambulance stretchers and wheelchairs will easily be able to enter and exit each birth room and the birth center by conducting a practice run with an ambulance service.

481—52.8(135G) Facility. All birth centers shall be designed, constructed, maintained, and operated to minimize the possibility of a fire or other life-threatening emergency to the staff and clients.

Hallways and doors providing entry and exit to the birth center and birth rooms shall be demonstrated to accommodate an ambulance stretcher.

An emergency power source shall be available that meets the fire marshal's requirements.

Written copies of a plan for evacuation in event of fire shall be available to all personnel. All personnel shall be instructed and kept informed of their responsibilities under the plan and supervised drills shall be conducted at least annually.

52.8(1) Patient care areas.

- a. Rescinded IAB 5/30/01, effective 7/4/01.
- b. The birth rooms shall be at least 120 square feet with at least 8-foot ceilings.
- c. A sink with hot and cold running water with elbow-wrist controls shall be in or adjacent to each birth room.

d. Fixed or portable toilets shall be available to the mother in labor. A separate toilet shall be available for family and staff use.

e. Bath or shower facilities shall be available to the mother in labor.

f. Separate segregated storage areas shall be available for:

- (1) Sterile supplies and equipment,
- (2) Clean supplies and equipment,
- (3) Janitorial supplies,
- (4) Soiled supplies and equipment.

g. Storage and disposal of waste materials shall be in compliance with 481—subrule 51.7(34).

h. A utility area shall be available for washing, sterilizing and handling of equipment. Sterilization may be done off the premises.

i. An area with easy access to birth rooms or in birth rooms shall be designated for emergency equipment, medication, and supplies outlined in protocols for practice.

j. Consultation and examination rooms shall be large enough to hold an examination table, stool, handwashing facilities, writing desk, and chairs. Privacy and confidentiality shall be ensured.

52.8(2) Office area. When business offices are part of the birth center facility the office suite shall have a closed door between the office area and the patient care area. The area designated as the business area shall include:

a. A reception area which is large enough to allow clients to wait in comfort.

b. A support service area such as a library, record storage area, staff office, and laboratory.

52.8(3) Equipment.

a. Birth room furnishings shall be constructed of materials that are easily cleaned and maintained and shall include:

- (1) A double bed or bed large enough to safely hold the mother and baby,
- (2) Comfortable chair or chairs,
- (3) Bedside and procedure table,
- (4) A bassinet,
- (5) Space for birth room supplies, equipment and family belongings.

b. The birth center may arrange for laundry to be done away from the birth center. If not, a washer and dryer shall be maintained in optimum working order. Clean linens shall be kept separated from soiled or contaminated linen.

c. Resuscitation equipment for both mother and infant.

(1) Infant. A table-like area of appropriate size and height shall be designated as an infant resuscitation area. This area shall have a radiant heat source fixed at the height recommended by the manufacturer. A resuscitation tray as described in protocols shall also be available in the area.

(2) Mother. Equipment for adult resuscitation as required by procedures outlined in protocols shall be maintained in an area convenient for emergency use.

d. Equipment needed to administer intravenous fluids shall be stored in an area convenient for emergency use.

e. A supply of oxygen shall be available for emergency use.

481—52.9(135G) Administration. A policy and procedure manual, adopted by the governing body, shall include all contracts and agreements of the birth center and shall be available for staff use and inspection by the department at all times. Policies and procedures shall also address provision of food for clients and their families, infection control, housekeeping, sanitation, disaster plans, medical record procedures, and criteria by which risk status will be established.

52.9(1) *Protocols for the management of routine and emergency care.* Protocols shall be developed by the director of medical affairs and the director or the director of midwifery services. They shall be available on site at all times. Annual review and revisions shall be documented.

a. Protocols shall address at least the following:

Provision of laboratory services,
Prenatal care,
Delivery care,
Emergencies with mothers,
Emergencies with infants,
Emergency transfers of mothers and infants,
Immediate postpartum care,
Newborn care,
Discharge criteria for the infant,
Discharge criteria for the mother,
Infection control.

b. Infection control protocols for handling of blood, body fluids, and body wastes shall be consistent with 1987 Center for Disease Control Guidelines published August 21, 1987, Vol. 36, No. 25 of Morbidity and Mortality Weekly Report available from U.S. Department of Health and Human Services, Public Health Services, Center for Disease Control, Atlanta, Georgia.

52.9(2) *Personnel policies.* Personnel policies shall include job descriptions for all personnel, description of required orientation, training and educational preparation. These policies shall be available on site.

52.9(3) *Management records.* The quality of the management of care of mothers, babies and families shall be evaluated by a review of records kept by staff of the birth center. A record of the following activities shall be included in the records, maintained on site, and made available for review by the department:

- a.* Regular staff meetings;
- b.* Case reviews, which must occur at least quarterly and must include all transfers and morbidity;
- c.* Midwifery audits conducted at least quarterly to evaluate the process and outcome of cases and client satisfaction;
- d.* Regular equipment maintenance; and
- e.* Drills for emergency procedures.

52.9(4) *Health records.* A health record shall list all services provided while the mother and fetus or newborn are under the care of the birth center. The record shall:

- a.* Be available at all times,
- b.* Include all reports of outside examinations or treatments and all related correspondence,
- c.* Be confidential and released only on the signature of the mother or, in the case of the baby, the signature of a parent or when the record is available by law according to Iowa Code section 135G.15(3) "*b*,"
- d.* Be made available to the department during licensure or complaint surveys,
- e.* Accompany, in copy form, the mother or newborn if either is transferred for other services,
- f.* Be stored in a secure manner and be readily retrievable,
- g.* Include:
 - (1) Identifying information,
 - (2) Risk assessments,
 - (3) Information relating to prenatal visits,
 - (4) Information relating to the course of labor and intrapartum care,
 - (5) Information relating to consultation, referral and transport to a hospital,
 - (6) Newborn assessment, Apgar score, record of required treatments and follow-up,
 - (7) Postpartum follow-up,
 - (8) Documentation of newborn metabolic testing as required by Iowa Code chapter 136A, and
- h.* Rescinded IAB 5/30/01, effective 7/4/01.

52.9(5) *Administrative records.* The birth center shall maintain state inspection reports which shall be made available to any person. The person requesting the report may be required to pay a reasonable fee to cover copying costs. Inspection reports shall be maintained in the records of the birth center for five years.

52.9(6) *Birth and death reports.* Certificates of births, newborn deaths and stillbirths shall be reported as required by Iowa Code chapter 144.

52.9(7) *Annual report.* An annual report shall be submitted to the department which shall include:

1. Number of clients,
2. Number of births, deaths and referrals, and
3. Reasons for the deaths and referrals.

The content of the annual report may result in further review by the department to determine if violations are occurring.

481—52.10(135G) *Services.* Each client, family or those otherwise identified by the client shall be fully informed of the policies and procedures of the licensed birth center, including, but not limited to:

1. The selection of clients,
2. The expectation for prenatal care and self-help involving the client and family,
3. The qualifications of the clinical staff,
4. Conditions which may result in a transfer to physician management or a hospital,
5. The philosophy of childbirth care practiced by the staff,
6. Services available, and
7. The customary length of stay after delivery.

52.10(1) *Informed consent.* No client shall be accepted for care at the birth center until she has signed a form indicating she has been informed of the possible risks and benefits of being enrolled in the birth center program for pregnancy and birth care. This form shall be developed by the department and used by the birth centers.

52.10(2) *Program of care.* The birth center shall provide at least:

- a. A record of the personal, medical and family history,
- b. A physical examination and laboratory tests,
- c. A continuous assessment of risk to mother and baby,
- d. Prenatal visits which comply with standards of the American College of Obstetricians and Gynecologists,
- e. Prenatal education that includes the importance of nutrition; information on adverse effects of smoking, alcohol and other drugs; preparation for birth; breast feeding; and care of the newborn,
- f. Intrapartum and postpartum services that foster parental control and responsibility in giving birth and bonding to the newborn,
- g. Labor support for the client and her family,
- h. Professional attendance at the birth, immediate postpartum care and newborn assessment, and
- i. Surveillance and documentation of fetal heart rate and uterine contractions during labor.

52.10(3) *Other services.* Services not provided by the birth center and available in the community shall be made available to clients through referral.

52.10(4) *Emergency consultation, referral and transfer.* Emergency consultation or referral and transfer to obstetric and pediatric care or hospital obstetrical and newborn services shall be provided by the center when, in the course of pregnancy, labor or postpartum, risk factors are identified which may preclude continuation of care by the center.

a. Circumstances which shall require physician consultation and may require transfer of a client to a hospital include, but are not limited to:

- (1) Inadequate progress in labor, suspected feto-pelvic disproportion or abnormal presentation,
- (2) Need for operative delivery,
- (3) Vaginal bleeding or unusual abdominal pain,
- (4) Indications of fetal distress,
- (5) Suspected amnionitis or sepsis,

- (6) Suspected systemic infection,
- (7) Umbilical cord prolapse, or
- (8) Any condition listed in rule 52.4(135G) which first appeared during labor.
- b.* Circumstances which require transfer of a newborn to a hospital shall include:
 - (1) Less than 37 weeks gestation with a birth weight less than 2500 grams,
 - (2) Respiratory distress or cyanosis lasting longer than 15 minutes,
 - (3) Exposure to infection,
 - (4) Neonatal seizures,
 - (5) Suspected neonatal sepsis or meningitis,
 - (6) Congenital anomalies requiring diagnostic evaluation or neonatal surgery,
 - (7) Meconium aspiration,
 - (8) An Apgar score of six or less at five minutes,
 - (9) Apnea,
 - (10) Gastrointestinal distress as exemplified by bilious vomiting, continuous vomiting, abdominal distention, or bloody diarrhea,
 - (11) Suspected hypoglycemia documented by dextro stick or other similar method.
- 52.10(5) *Surgical procedures.*** Surgical procedures shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair. Other surgical procedures such as forceps, tubal ligation, abortion, or Cesarean section shall not be performed in birth centers.
- 52.10(6) *Analgesia and anesthesia.*** Pain control shall depend primarily on close human support, psychological analgesia and adequate preparation for the birth experience. Local anesthesia for pudendal block and episiotomy and repair may be administered according to procedures outlined in approved protocols.
- 52.10(7) *Chemical agents.*** Labor may not be stimulated or augmented with chemical agents. Labor may be inhibited with chemical agents only when prescribed by a physician in anticipation of an emergency transfer.
- 52.10(8) *Discharge follow-up.*** A mother and her infant shall be dismissed within 24 hours after the birth of the infant. If a mother or infant is retained at the birth center for more than 24 hours after the birth, a report shall be filed with the department within 48 hours of the birth describing the circumstances and the reasons for the decisions.
 - a.* A prophylactic shall be instilled in the eyes of each newborn in accordance with Iowa Code section 140.13.
 - b.* Postpartum evaluation and follow-up care shall be provided, which shall include:
 - (1) A physical examination of the infant,
 - (2) Metabolic screening tests required by Iowa Code chapter 136A,
 - (3) Referral to sources for pediatric care,
 - (4) Maternal postpartum assessment,
 - (5) Instruction in child care, including immunizations,
 - (6) Family planning services, and
 - (7) Referral to a licensed hospital.

481—52.11(135G) *Evaluation.* The birth center shall have available on-site reports of periodic self-evaluation of the service that shall include, but not be limited to:

- 1. Demonstration of how program goals and objectives are being met;
- 2. Analysis of data collected on use of services and outcomes for mothers and babies;
- 3. Determination of client satisfaction.

These rules are intended to implement Iowa Code chapter 135G.

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